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10/583,034

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Philippe Gauthier

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EXAMINER

HOLLERAN, ANNE L

ART UNIT

PAPER NUMBER

1643

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/583,034 | <b>Applicant(s)</b><br>GAUTHIER ET AL. |  |
|                              | <b>Examiner</b><br>ANNE L. HOLLERAN  | <b>Art Unit</b><br>1643                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 8 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

The amendment filed 1/05/2010 is acknowledged.

Claims 1-8 are pending and examined on the merits.

***Claim Objections/Rejections Withdrawn:***

***Claim Objections***

The objection to claim 1 because of informalities is withdrawn in view of the amendment to the claim.

The objection to claims 5 and 6 for a typographical error is withdrawn in view of the amendment to the claims.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1 and 8 under 35 U.S.C. 103(a) as being unpatentable over Baral (Baral, R. et al., Int. J. Cancer, 92: 88-95, 2001; cited in the IDS), in view of Fengtian (Fengtian, H. et al., Chin. Med. Sci. J. 17(4): 215-219, 2002; of record) or Tripathi (Tripathi, P.K., et al., Molecular Immunology, 35: 853-863, 1998), and further in view of Marks (Marks, J.D. et al., J. Mol. Biol., 222(3): 581-597, 1991; of record) is withdrawn in view of the amendment to the claims.

The rejection of claims 1, 4 and 8 under 35 U.S.C. 103(a) as being unpatentable over Baral (Baral, R. et al., Int. J. Cancer, 92: 88-95, 2001; cited in the IDS), in view of Fengtian (Fengtian, H. et al., Chin. Med. Sci. J. 17(4): 215-219, 2002; of record) or Tripathi (Tripathi,

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P.K., et al., Molecular Immunology, 35: 853-863, 1998), in view of Marks (Marks, J.D. et al., J. Mol. Biol., 222(3): 581-597, 1991; of record), and further in view of Cho (Cho, H.-S. et al., Nature, 421: 756-760, 2003, February) is withdrawn in view of the amendment to the claims.

The rejection of claims 1, 7 and 8 under 35 U.S.C. 103(a) as being unpatentable over Baral (Baral, R. et al., Int. J. Cancer, 92: 88-95, 2001; cited in the IDS), in view of Fengtian (Fengtian, H. et al., Chin. Med. Sci. J. 17(4): 215-219, 2002; of record) or Tripathi (Tripathi, P.K., et al., Molecular Immunology, 35: 853-863, 1998), in view of Marks (Marks, J.D. et al., J. Mol. Biol., 222(3): 581-597, 1991; of record), and further in view of Todorovska (Todorovska, A. et al., Journal of Immunological Methods, 248: 47-66, 2001) is withdrawn in view of the amendment to the claims.

***Claim Rejections Maintained:***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7 and 8 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because of the phrase “which is capable of mimicking Her-2/neu tumor associated antigen”, because this is not a positive recitation of the function of mimicking Her-2/neu. Therefore, it is not clear if the claim is limited to those species which in fact mimic

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Her-2/neu. Amendment to recite: "which mimics Her-2/neu tumor associated antigen" is suggested.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1-3, 7 and 8 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for anti-idiotypic antibody Fabs or scFvs that mimic Her-2/neu, such as scFv40 comprising SEQ ID NO: 1, or scFv69, comprising SEQ ID NO: 2, does not reasonably provide enablement for broadly recited anti-idiotypic antibody Fab- and scFv-fragments, which are capable of mimicking any epitope on the Her-2/neu tumor associated antigen, and also comprise the specific set of listed CDR sequences. One of skill in the art would not know how to use the full scope of the claimed invention because "capable of mimicking" is a phrase that does not clearly define a genus of antibodies that mimic Her-2/neu. One of skill in the art would not know how to make the full scope of the claimed invention because the recited anti-idiotypic antibodies comprise sets of CDRs that are found in antibodies that bind to trastuzumab F(ab')<sub>2</sub>, which binds to a single epitope on the Her-2/neu antigen, whereas the claims encompass anti-idiotypic antibodies that bind to any anti-Her-2/neu antibody.**

The claims are drawn to a human idiotypic antibody Fab- or scFv-fragment that comprises CDR sequences SEQ ID NO: 15, SEQ ID NO: 16, SEQ IDNO: 17, SEQ ID NO: 18 and (i) SEQ ID NO: 3 and SEQ ID NO: 4, or (ii) SEQ ID NO: 5 and SEQ ID NO: 6. These two

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sets of CDR sequences are from the scFvs designated scFv 40 and scFv 69, which are scFvs that bind to trastuzumab F(Ab')<sub>2</sub>, which binds to a particular epitope on Her2/neu. Her2/neu is a transmembrane protein that comprises multiple epitopes (see Albanell, J., et al, Mechanism of Action of Anti-Her-2 Monoclonal Antibodies: Scientific Update on Trastuzumab and 2C4, in: New Trends in Cancer for the 21st Century, ed. Llombart-Bosch and Felipo, Kluwer Academic/Plenum, 2003: pages 253-268; and see Klapper, L.N., et al., Oncogene, 14: 2099-2109, 1997). The disclosure of the specification of the particular sets of CDRs or of the entire scFv structures of scFv 40 and scFv69 does not allow one of skill in the art to make antibodies that bind to anti-Her2/neu antibodies other than trastuzumab F(ab')<sub>2</sub> because the specification has not taught how changes in the framework amino acid structure can be made to change specificity of an antibody, which is what would be required for the full scope of the claims, drawn to anti-idiotypic antibodies that bind to any anti-Her2/neu antibody.

The claims are drawn to antibodies capable of mimicking Her2/neu antigen, wherein the antibodies comprise a particular set of CDR sequences. Capable of mimicking is a phrase that implies that there are circumstances where the antibody actually mimics and other circumstances where the antibody does not mimic Her-2/neu antigen. Thus, the claims encompass non-functional antibodies that the specification has not taught one of skill in the art how to use.

In both cases set forth above, one of skill in the art would be required to engage in further experimentation to practice the full scope of the claims, and this further experimentation would be undue experimentation because it would require experimenting on the invention itself without any guidance from the prior art or from the specification. Therefore, the rejection of record is maintained for the reasons of record.

***Conclusion***

No claim is allowed. Claims 5 and 6, which are free of the art, are objected to for being dependent from rejected claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran  
Patent Examiner  
/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643